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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/584,821	03/13/2008	Emile M. Bellott	MLA.028NP	5573

20995 7590 06/25/2010

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EXAMINER	
SHEN, BIN	

ART UNIT	PAPER NUMBER
1657	

NOTIFICATION DATE	DELIVERY MODE
06/25/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/584,821	BELLOTT ET AL.	
	Examiner	Art Unit	
	BIN SHEN	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 May 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-17 and 20-24* is/are pending in the application.

4a) Of the above claim(s) *14 and 16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12,13,15,17 and 20-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 June 2006* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/25/2007, 5/4/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Notice to Comply*.

DETAILED ACTION

The IDS received 5/25/2007, 5/4/2010, the preliminary amendment received 6/26/2006 has been entered.

Election

Applicant's election without traverse of Group I, claims 12, 13-17, and election of species of epidermis, CF_3 for R_9, H for R_{10}, R_{11}, R_{13}, and M for R_{12}, in the reply filed on 5/4/2010 is acknowledged.

Search was performed for the elected species for the compound: CF_3 for R_9, H for R_{10}, R_{11}, R_{13}, and M for $R_{12,}$ which was deemed free of prior art. Search was then extended as stated in MPEP § 803.02: "Should the examiner determine that the elected species is allowable, the examination of the Markush-type claim will be extended. If prior art is then found that anticipates or renders obvious the Markush-type claim with respect to nonelected species, the Markush-type claim shall be rejected and claims to the nonelected species held withdrawn from further consideration. The prior art search, however, will not be extended unnecessarily to cover all nonelected species." For Markush type compound of claim 1, prior art was found that anticipated compound of claim 1. Since prior art reads on the claimed compound (CH_3 for R_9, H for R_{10}, R_{11}, OH for R_{13} in Kataoka-see below), those claims have been rejected.

Rejoinder

Since a non-elected species (of the Markush group) of the compound was found, thus the compound claims 22-24 are rejoined. Claims 14, 16 are drawn to non-elected species, and thus are withdrawn from further consideration.

Claims 12-13, 15, 17 and 20-24 are presented for examination on the merits.

Priority

Priority to 12/24/2003 is acknowledged.

Sequence to comply

This application contains sequence disclosures in Fig. 34 of the Drawings of the specification that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a((1) and (a)(2). However, this application fails to comply with one or more of the requirements of 37 C.F.R. § 1.821 through 1.825 for one or more of the reasons set forth on the attached form "Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequences And/Or Amino Acid Sequence Disclosures". Wherein attention is directed to paragraph(s) §1.82 (c) and (e). Although an examination of this application on the merits can proceed without prior compliance, compliance with the Sequence Rules is required for the response to this Office action to be complete.

Specification

The abstract of the disclosure is objected to because the abstract must be a single paragraph. Correction is required. See MPEP § 608.01(b).

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

This application does not contain an abstract of the disclosure as required by 37 CFR 1.772(b). An abstract on a separate sheet is required to replace the provided abstract of the WO file front of the parent PCT.

Drawings

The drawings are objected to because the amino acid sequences in Fig. 34 of the Drawings are not identified by SEQ ID NO#, and a "Sequence Listing" is not provided together with a statement that the paper copy and the computer readable copy are identical . Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance. Alternatively, the SEQ ID NOs can be placed in the Brief Description of the Drawings.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 22-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Samankumara Sandanayake (1995).

Sandanayake teaches fluorescence intensity and spectral changes of a 7-aminocoumarin moiety with a neighboring boronic group upon saccharide binding which could be used in fluorescence mapping of saccharides in cells (page 139, right column, Scheme 1). The coumarin

based molecular fluorescence sensor 1 (page 139, left column) reads on a non-elected species of the claimed compound (because CF_3 is not R_9 but rather CH_3, H for R_{10}, R_{11}, R_{13}, and M for R_{12}).

Therefore, Sandanayake teaches a method of measuring saccharide including glucose (a compound or metabolite, page 140, Fig. 2), comprising: contacting compound of Scheme 1 (a reporter compound or a salt thereof) with different saccharide; and detecting a photometric change in the reporter compound that is indicative of the saccharide-glucose (page 140, Fig. 2); wherein the compound is glucose (page 140, Fig. 2, **Claim 21).** Sandanayake suggests that this method could be used for mapping and etecting saccharides in cells (page 140, last paragraph, **Claim 20**)

Therefore, Sandanayake also teaches a compound (fluorescence sensor 1 on page 139, left column) of **Claim 22** wherein D is O, R_9 is CH_3, R_{10}, R_{11}, R_{13}, are H, and M for $R_{12,}$ L is an amino-containing linking moiety and one boronic acid moiety is present, wherein the amino-containing linking moiety L is a substituted amino group (**Claim 23**).

Claims 22-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Kataoka (1995).

Kataoka teaches fluorescence intensity and spectral changes of a PAPBA/DHMC complex (page 1146, Fig. 1) upon glucose binding which could be used in fluorescence measuring of glucose (page 1147, left column, Fig. 4). The PAPBA/DHMC complex (page 1146, left column, Fig. 1) reads on the claimed compound (non-elected species wherein CH_3 is R_9, and OH is R_{13}).

Therefore, Kataoka teaches a method measuring glucose (a compound or metabolite, page 1147, Fig. 4), comprising: contacting PAPBA/DHMC complex (a reporter compound or a salt thereof) with glucose solution and detecting a photometric change in the reporter compound that is indicative of the saccharide-glucose (page 1147, Fig. 4); wherein the compound or metabolite is glucose (**Claim 21**). Kataoka suggests that this method could be used to measure glucose in blood (page 1147, column 1, **Claim 20**).

Therefore, Kataoka also teaches a compound (page 1146, left column, Fig. 1) of **claim 22** wherein D is O, R_9 is CH_3, R_{10}, R_{11}, are H, R_{13} is OH, and M for $R_{12,}$ L is an amino-containing linking moiety (page 1146, left column, Scheme 1 structure of PAPBA on the left) and one

boronic acid moiety is present, wherein the amino-containing linking moiety L moiety (page 1146, left column, Scheme 1 structure of PAPBA on the left) is a substituted/unsubstituted amino group (**Claim 23**).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 12-13, 15, 17 and 20-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Kataoka or Sandanayake and Koschinsky (2001).

Kataoka and Sandanayake both teach the measurement of glucose with the claimed reporter compound and suggest detecting or measuring glucose in blood and cells.

Kataoka and Sandanayake do not teach contacting the reporter compound directly with body/skin to measure glucose, or a reagent strip comprising the claimed compound.

Koschinsky teaches optical measurement of glucose through contacting skin with glucose sensor test strip (Claims 12, 13,).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Sandanayake or Kataoka by using the reporter compound as a glucose sensor on a reagent strip (**Claim 24**) to measure skin/epidermis glucose (**Claims 12, 13, 15, 17**) because Koschinsky teaches the use of glucose sensor inserted into skin for glucose detection (page 118, left column, lines 1-3). One would have been motivated to make the modification because Sandanayake or Kataoka et al. specifically described a reporter compound that can be used to measure glucose, and would reasonably have expected success in view of Koschinsky's teaching of optical changes (page 114, right column, 4th full paragraph, lines 3-5) of glucose sensor insertion into skin for glucose detection. A person of ordinary skill in the art upon reading the cited reference, would also recognized the desirability of improved the method by using the glucose sensor in a reagent strip format for convenient testing because a test strip is

the most common testing method that will lead to the anticipated success. Thus it is likely a reagent strip comprising the claimed compound not of innovation but of ordinary skill and common sense.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

No claim is allowed.

Art of Record:

Sandanayake (1995) teaches fluorescence intensity and spectral changes of a 7-aminocoumarin moiety with a neighboring boronic group upon saccharide binding which could be used in fluorescence mapping of saccharides in cells (page 139, right column, Scheme 1). The coumarin based molecular fluorescence sensor 1 (page 139, left column) reads on a non-elected species of the claimed compound (because CF_3 is not R_9 but rather CH_3, H for R_{10}, R_{11}, R_{13}, and M for R_{12}).

Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Bin Shen, whose telephone number is (571) 272-9040. The examiner can normally be reached on Monday through Friday, from about 9:00 AM to about 5:30 PM. A phone message left at this number will be responded to as soon as possible (i.e., shortly after the examiner returns to her office).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at (571) 272-0925.

B Shen
Art Unit 1657

/JON P WEBER/
Supervisory Patent Examiner, Art Unit 1657